EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt.: 1:13-md-02419-FDS
THIS DOCUMENT RELATES TO: All Actions	

ORDER GRANTING PLAINTIFFS LEAVE TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE ORDER REGARDING PROTECTION OF HEALTH INFORMATION

WHEREAS, the Court recognizes that protected health information may be produced in response to subpoenas issued by parties in the MDL;

WHEREAS, nothing in this order shall deprive a subpoena recipient of the opportunity to object to requests to produce such protected information;

WHEREAS, the Court desires to establish an up-front process for the production of any such protected health information in compliance with applicable federal and state law.

IT IS HEREBY ORDERED that "Personal Health Information," and "individually identifiable health information" protected under the Health Insurance Portability and Accountability Act of 1996 (hereinafter "HIPAA") (42 USC §1320d et seq.) and the regulations promulgated thereunder (45 CFR §§160, 164 et seq.), shall only be disclosed as follows:

1. Healthcare facilities and/or providers that have examined, tested or treated patients who have been identified as recipients of one or more of New England Compounding Pharmacy, Inc. ("NECC") solutions, medications or compounds, shall produce protected health information pursuant to this order and a subpoena issued by Plaintiffs.

2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 – November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

3. All protected health information produced pursuant to this order shall be produced in electronic or hard copy format only to a third party vendor (the "Vendor") to be selected jointly by the Plaintiffs' Steering Committee, the chapter 11 trustee appointed in NECC's chapter 11 case (the "Trustee"), and the Official Committee of Unsecured Creditors appointed in NECC's chapter 11 case (the "Official Committee"), after meeting and conferring.

4. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court.

5. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

6. The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose. In the event Defendants wish to use documents, data or other information produced pursuant to the subpoenas and this Order, they may seek permission of the Court to do so.

7. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.

8. Nothing in this Order authorizes direct communications between defendants, their counsel or other agents or representatives and the patients' healthcare providers providing disclosure pursuant to this Order, nor does it bar such communications.

9. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

10. Plaintiffs' Counsel are authorized to serve subpoenas issued by this Court on the entities listed in NECC's Customer list located at: http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf as well as Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.

11. All subpoenaed entities that provide requested information shall be deemed to fall within the safe harbor of HIPAA for court-ordered production of personal health information, 45 C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state statute, regulation, or other requirement related to protected health information, for supplying patient or member information to the Vendor.

12. The Vendor shall not be deemed to be a guarantor of the completeness and accuracy of the data provided to it and shall have the right to rely in good faith upon the information provided by any subpoenaed entity.

13. The subpoenaed entities are to use their best effort to supply the requested information.

14. The subpoenaed entities must produce the requested information to the Vendor within 30 days of receipt of the subpoena.

15. A copy of this Order shall be appended to the subpoenas.

SO ORDERED.

Dated this 21st day of June, 2013.

/s/ F. Dennis Saylor
F. Dennis Saylor, IV
United States District Judge

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June 24, 2013

Premier Orthopedic and Sports Medicine
Associates of Southern New Jersey, LLC
c/o Jay J. Blumberg, Esquire
Law Offices of Jay Blumberg
158 Delaware Street
PO Box 68
Woodbury, NJ 08096

Re: New England Compounding Center Litigation, MDL No. 2419

To Mr. Blumberg:

As you are aware, last year New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center ("NECC") distributed tainted medication to various clinics throughout the country and specifically in New Jersey. Hundreds, if not thousands, of patients have been injured as a result of exposure to tainted NECC products. The most recent Center for Disease Control reports confirm that over 700 patients have confirmed illnesses related to their exposure to tainted NECC pharmaceuticals and over 240 people have confirmed cases of meningitis. Fifty-eight people have died.

According to the CDC, Premier Orthopedic and Sports Medicine Associates of Southern New Jersey, LLC purchased and received preservative free methylprednisolone actetate from at least one of the three contaminated lots distributed by NECC.

The Judicial Panel on Multidistrict Litigation created a multi-district litigation forum in the United States District Court for the District of Massachusetts to address federal lawsuits alleging harm related to products manufactured by NECC (No. 1:13-md-2419-FDS). The Honorable Judge Saylor appointed seven firms to the Plaintiffs' Steering Committee (PSC) and appointed me, Thomas M. Sobol of Hagens Berman Sobol Shapiro LLP, as Lead Counsel.

Lead Counsel and the PSC are charged with:

1. Initiating, coordinating, and conducting all pretrial discovery on behalf of plaintiffs in all actions subject to this order;

2. Developing and proposing to the Court schedules for the commencement, execution, and completion of all discovery on behalf of all plaintiffs;

3. Issuing in the name of all plaintiffs the necessary discovery requests, motions, and subpoenas concerning any witnesses and documents needed to prepare for the trial of this litigation (similar requests, motions, and subpoenas may be caused to be issued by the PSC upon written request by an individual attorney in order to assist him or her in the preparation of the pretrial stages of his or her client's particular claims); and

4. Conducting all discovery, by members or their designees approved by Lead Counsel, in a coordinated and consolidated manner on behalf and for the benefit of all plaintiffs.

NECC has filed for reorganization under Chapter 11 of the Bankruptcy Code. Lead Counsel and the PSC are coordinating their efforts with the Official Creditor's Committee and its counsel, and will share with the Creditor's Committee all appropriate information that you produce in response to the subpoena. The PSC and Lead Counsel are committed to working hand-in-hand with the Official Creditors' Committee. Lead Counsel and the Creditors' Committee will be involved in any settlement discussions.

Lead Counsel and the PSC have designated Richard M. Golomb and Steven D. Resnick of Golomb & Honik, P.C. to handle the day-to-day litigation of claims against Premier Orthopedic and Sports Medicine Associates of Southern New Jersey, LLC.

You will receive a subpoena requesting information about your purchase, storage, and use of NECC products shortly. For your convenience, a copy of that subpoena is attached.

The subpoena requests some information that is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other privacy laws. Judge Saylor entered an order in the MDL governing the production of this protected health information. (Dkt. No. 192) We will identify a HIPAA-compliant vendor to

receive (only) protected health information that is responsive to this subpoena. All other responsive information should be produced in accordance with the instructions in the subpoena.

Judge Saylor has entered an order confirming that he will centrally enforce all subpoenas and instructing subpoena recipients to file any objections or motions to quash directly into the MDL. (Dkt. No. 193) Judge Saylor will hear any objections to subpoenas at the July 18, 2013 MDL status conference. (Dkt. No. 193).

Thank you. Please contact me or Steven D. Resnick with any questions.

Sincerely,

/s/ Thomas M. Sobol

Thomas M. Sobol
Partner
HAGENS BERMAN SOBOL SHAPIRO LLP

TMS:kjp
Enclosure

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In re: New England Compounding Pharmacy, Inc.
Plaintiff
v.
Defendant

Civil Action No. MDL 1:13-md-02419

(If the action is pending in another district, state where:)

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Premier Orthopedic and Sports Medicine Associates of Southern New Jersey, LLC, c/o Jay J. Blumberg, Esquire, Law Offices of Jay Blumberg, 158 Delaware Street, PO Box 68, Woodbury, NJ 08096

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: See Exhibit "A" attached

Place:	Date and Time:
Golomb & Honik, PC, 1515 Market Street, Suite 1100, Philadelphia, PA 19102	07/15/2013 10:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 06/25/2013

CLERK OF COURT

Signature of Clerk or Deputy Clerk

OR

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* Plaintiff's Steering Committee, who issues or requests this subpoena, are:

Patrick T. Fennell, Esquire, Crandall & Katt, 374 Elm Avenue SW, Roanoke, VA 24016; 540-342-2000

Civil Action No. MDL 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

☐ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

☐ I returned the subpoena unexecuted because: _____

_____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of

$ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction -- which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Exhibit A to Subpoena

1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied).

2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for opthalmic solution (before and after any discounts applied).

5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the

foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

7. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between Premier Orthopedic and Sports Medicine Associates of Southern New Jersey, LLC "Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

8. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

9. Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

11. Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

12. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

13. Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

14. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

15. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

16. Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled "Pharmaceutical Compounding – Sterile Preparations").

17. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

18. Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

20. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

21. Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

All Defense Counsel of record in MDL 2419

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NEW JERSEY CLINIC SERVED WITH SUBPOENA IN LITIGATION INVOLVING MENINGITIS OUTBREAK

Discovery begins in cases consolidated in U.S. District Court in Massachusetts

FOR IMMEDIATE RELEASE: June 26, 2013
CONTACT: Steven D. Resnick, Telephone: 215-985-9177, E-mail: sresnick@golombhonik.com

(Vineland, NJ) June 26, 2013. Today, Premier Orthopaedic Associates, a pain management clinic in Vineland, was served with a subpoena requiring it to turn over documents in its possession that could shed light on allegations that its patients received injections of tainted medication that led to serious illness.

The subpoena originated in the U.S. District Court for the District of Massachusetts, which is overseeing the consolidation of most cases in Federal and state court alleging personal injury or wrongful death as a result of the contaminated injections. The subpoena was issued by attorneys working in conjunction with a seven-member Plaintiffs' Steering Committee appointed by the District Court to initiate, coordinate and conduct all pretrial discovery of plaintiffs in all actions pending in that court. The purpose of the subpoena is to investigate facts material to ongoing proceedings in the consolidated cases in Massachusetts, and does not necessarily indicate wrongdoing on the part of the clinic. The issuance of the subpoena should not be interpreted as an allegation of wrongdoing on the part of the clinic.

Premier Orthopaedic Associates was one of many clinics nationwide identified by the Centers for Disease Control and Prevention (CDC) as having purchased and administered vials of contaminated methylprednisolone acetate ("MPA") that were produced by New England Compounding Pharmacy, Inc. (NECP) of Framingham, Massachusetts. This is one of many subpoenas being served nationwide on most of the approximately 76 clinics across the country that have been identified as having dispensed NECP products. The CDC has reported 51 cases of fungal meningitis infection, linked to the tainted compound, in the State of New Jersey alone.

The subpoena requires Premier Orthopeedic Associates to produce for examination or copying, documents and communications between the clinic and NECP, including information reflecting purchasing decisions, items purchased, dates, quantities, pricing, storage of the medication and more.

According to Steven Resnick, this subpoena signals the next step of an ongoing investigation of the role clinics like Insight Imaging played in the distribution of contaminated medication. "We believe the information we receive from Insight Imaging will help us understand how the outbreak of fungal meningitis infections occurred," Steven Resnick said.

The outbreak of fungal meningitis infections is the worst such outbreak in U.S. history. The CDC has recorded more than 700 infections nationwide, and has not ruled out the possibility that this number will continue to grow.

As a result of the large number of actual and anticipated civil lawsuits arising from the outbreak, NECP filed for reorganization under Chapter 11 of the United State Bankruptcy Code, in the U.S. Bankruptcy Court in Massachusetts, on December 21, 2012. On February 12, 2013, the United States Judicial Panel on Multidistrict Litigation ordered the consolidation of all Federal cases in the U.S. District Court in Massachusetts.

On April 9, 2013 the Hon. F. Dennis Saylor, IV, presiding United States District Court Judge, appointed the Plaintiffs' Steering Committee, of which Thomas M. Sobol, an attorney with the firm Hagens Berman Sobol Shapiro LLP, is lead counsel. Richard M. Golomb and Steven D. Resnick are working with the Plaintiffs' Steering Committee to organize the litigation in the State of New Jersey.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt.: 1:13-md-02419-FDS
THIS DOCUMENT RELATES TO: All Actions	

ORDER ON
CENTRAL ENFORCEMENT OF SUBPOENAS

WHEREAS the Plaintiffs' Steering Committee has advised the Court that it intends to issue subpoenas to:

- Pain clinics, hospitals, and other entities or individuals who purchased NECC's methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution;
- Vendors and contractors who worked on or were responsible for the conditions of the NECC facility;
- Vendors who conducted sterility or other testing of NECC's products or equipment used to make the products; and
- Suppliers who provided the raw materials used to create methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution.

WHEREAS the Court has the authority to enforce subpoenas issued out of the MDL;

WHEREAS the Court finds that central enforcement of these subpoenas will promote efficiency and the interests of justice;

IT IS HEREBY ORDERED

1. This Court will centrally enforce subpoenas issued out of the MDL.

2. Any objections or motions to quash subpoenas issued out of the MDL shall be filed directly into the MDL. Attorneys are permitted to make a limited appearance for the purposes of contesting a subpoena without being deemed to otherwise consent to the jurisdiction of this Court.

3. Objections to subpoenas served before July 10, 2013 will be heard during the July 18, 2013 status conference.

SO ORDERED.

Dated this 21st day of June, 2013.

/s/ F. Dennis Saylor
F. Dennis Saylor, IV
United States District Judge

EXHIBIT B

This is an official

CDC Health Advisory

Distributed via Health Alert Network
October 17, 2012, 13:15 (1:15 PM ET)
CDCHAN-00329-2012-10-17-UPD-N

Update: Multistate Outbreak of Fungal Meningitis and Joint Infections Associated with Contaminated Steroid Medications

Summary

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to work closely with state public health departments on a multistate investigation of fungal meningitis and joint infections among patients who received a methylprednisolone acetate injection prepared by the New England Compounding Center (NECC) in Framingham, Mass. Some of these patients who received epidural injections also suffered strokes that may have resulted from their infection. This HAN notice provides updated information on the following:

- Status of the investigation.
- FDA issuance of a MedWatch Safety Alert on October 15 advising clinicians to follow-up with patients who received an injectable NECC product, including any ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012.
- Recommendations for clinicians.
- Case definition.

Background

CDC, in collaboration with FDA, state public health departments, and state boards of pharmacy, has been investigating an ongoing outbreak of fungal infections associated with a contaminated steroid medication, preservative-free methylprednisolone acetate (80mg/ml) prepared by the New England Compounding Center, in Framingham, Mass. CDC and state public health departments are actively coordinating outreach to patients who have been exposed to this contaminated medication.

As of October 16, 2012, a total of 233 cases, which includes 2 peripheral joint infections and15 deaths, have been reported in 15 states (see CDC's website for up-to-date information about case count and distribution by state). The fungus *Exserohilum rostratum* has been reported in clinical specimens from multiple patients with fungal meningitis and with other spinal infections (e.g., epidural abscess). CDC and FDA continue to investigate the possibility of contamination with additional organisms. At this time, one clinical specimen has tested positive for the fungus *Aspergillus fumigatus*, and another has tested positive for the fungus *Cladosporium*. Fungal meningitis is not transmitted from person to person.

The clinical presentation of infected patients with fungal meningitis remains consistent with that described in previous reports: onset of symptoms is typically between 1 to 4 weeks following injection with a variety of symptoms, including fever, new or worsening headache, nausea, and new neurological deficit (consistent with deep brain stroke). However, fungal infections can be slow to develop, and there are reports of longer periods between injection and onset of symptoms; and, therefore, patients and their doctors need to watch closely for symptoms for at least several months following the injection. Some of these patients' symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically had an elevated white cell count (usually with a predominance of neutrophils), and in many cases low glucose and elevated protein. As of October 16, two peripheral joint infections have

been reported. CDC expects that through ongoing patient notification efforts, additional patients with infections of the joints may come forward.

On September 26, 2012, NECC voluntarily recalled the following lots of methylprednisolone acetate (PF) 80mg/ml:

- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

On October 6, NECC expanded its previous recalls to include all products currently in circulation that were compounded at and distributed from its facility in Framingham, Mass. More information about this recall is available at the FDA website.

All cases reported as of October 16 have occurred after injections with methylprednisolone acetate products from one of the three lots recalled on September 26.

FDA MedWatch: Additional NECC Products of Potential Concern

On October 15, FDA released a MedWatch Safety Alert announcing that, as a result of the ongoing investigation of NECC, a patient with possible fungal meningitis who had received an epidural injection of triamcinolone acetonide produced by NECC has been identified through active surveillance efforts by CDC and state health departments and reported to FDA. Triamcinolone acetate is a type of steroid injectable product made by NECC. As of October 17, there is no laboratory evidence of fungal infection in this patient. As noted above, all cases of fungal meningitis identified to date have been associated with methylprednisolone acetate, another similar steroid injectable product distributed by NECC.

In addition, FDA received a report of one cardiac transplant patient with *Aspergillus fumigatus* infection who was administered NECC cardioplegic solution, which is used to prevent injury to the heart during surgery. Investigation of this patient is ongoing; there may be other explanations for this patient's *Aspergillus* infection.

This is preliminary information and CDC does not have firm evidence that infections have been caused by exposure to NECC products beyond the three previously listed lots of methylprednisolone acetate. Out of an abundance of caution, FDA has advised clinicians to follow up with patients to whom they have administered an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012.

Clinicians should perform a thorough diagnostic evaluation to exclude infection in those patients who report signs and symptoms of infection following high-risk exposure to one of these NECC products (e.g., exposure of product to sterile body site). If the evaluation of these patients is suggestive of fungal infection, please consult existing CDC treatment guidance http://www.cdc.gov/hai/outbreaks/clinicians/index.html. Consultation with an infectious disease specialist is strongly encouraged to help make treatment decisions in these cases.

Products from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo that can be accessed here. Additional information about the MedWatch Safety Alert notice is available on the FDA website.

Recommendations for Clinicians

CDC and FDA have three recommendations for clinicians.

1. Clinicians should contact (by phone or in person) any patient who had an injection (e.g., spinal, joint) after May 21, 2012, using any of the following three recalled lots of preservative-free methylprednisolone acetate (80mg/ml) produced by NECC, to determine if they are having symptoms:

   - Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 05212012@68, BUD 11/17/2012
   - Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot#06292012@26, BUD 12/26/2012
   - Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 08102012@51, BUD 2/6/2013

   Symptoms that should prompt diagnostic evaluation include fever, new or worsening headache, neck stiffness, sensitivity to light, new weakness or numbness, increasing pain, redness or swelling at injection site. Some of the symptoms of patients who have ultimately been diagnosed with fungal meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness).

2. Healthcare professionals should cease use of **any** product produced by NECC, all of which have been recalled.

   - Through its investigation of the NECC facility, FDA cannot confirm the sterility of any of the NECC products. On October 15, FDA issued a MedWatch Safety Alert advising clinicians to follow-up with patients who received an injectable NECC product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012. Clinicians are also requested to report any suspected adverse events following use of these products to FDA's MedWatch program at **1-800-332-1088** or www.fda.gov/medwatch

   As in the past, CDC continues to recommend that clinicians remain vigilant for any possible adverse events related to the use of any NECC product. Clinicians are encouraged to report such events to their state public health department.

3. CDC will continue to update clinical guidance as more information becomes available. As of October 16, CDC has updated clinician guidance addressing:

   - Interim Treatment Guidance for Central Nervous System (CNS) and/or Parameningeal Infections Associated with Injection of Potentially Contaminated Steroid Products
   - Interim Treatment Guidance for Septic Arthritis Associated with Injection of Potentially Contaminated Steroid Products
   - Interim Guidance for Management of Asymptomatic Persons Exposed to Potentially Contaminated Steroid Products
   - Diagnostic Testing for Septic Arthritis and Specimen Submission to CDC – Outbreak Associated with Injection of Potentially Contaminated Steroid Products
   - Instructions for Clinicians Regarding Diagnostic Testing and Specimen Shipping for Central Nervous System and/or Parameningeal Infections
   - Role of Antifungal Prophylaxis in Asymptomatic Patients

CDC Case Definitions

The current investigation is a rapidly evolving situation and information about cases continues to be updated. For the most recent information about case definitions, please see CDC's clinical guidance web

page at http://www.cdc.gov/hai/outbreaks/clinicians/casedef_multistate_outbreak.html.

Additional Information

- Multistate Fungal Meningitis Outbreak Investigation
- MMWR Early Release: Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharmacy — United States, 2012.
- CDC HAN Advisory: Meningitis and Stroke Associated with Potentially Contaminated Product
- CDC HAN Advisory: Update: Multistate Outbreak of Meningitis and Stroke Associated with Potentially Contaminated Steroid Medication
- CDC Website on Fungal Diseases
- FDA Statement on Fungal Meningitis Outbreak

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Categories of Health Alert messages:

Health Alert	conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	provides important information for a specific incident or situation; may not require immediate action.
Health Update	provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##

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